

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/592,007	06/12/00	TOFARO	F 08582/009002

PAUL T CLARK ESQ
CLARK & ELBING L L P
176 FEDERAL STREET
BOSTON MA 02110

HZ12/0925

 EXAMINER

WANG, A

ART UNIT	PAPER NUMBER
1635	5

DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/592,007

Applicant(s)

TUFARO ET AL.

Examiner

Andrew Wang

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed

- after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-27 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claims ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. ____.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**KATRINA TURNER
PATENT ANALYST****Attachment(s)**

15) Notice of References Cited (PTO-892) ✓

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

18) Interview Summary (PTO-413) Paper No(s) ____.

19) Notice of Informal Patent Application (PTO-152)

20) Other: ____

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,13, 14, 16, and 18-27 rejected under 35 U.S.C. 102(b) as being anticipated by Dyer et al.

Dyer et al. disclose the use of dextran sulfate to deliver an HSV vector comprising a gene to cells.

Therefore, the invention of the above claims have been anticipated.

Claims 1-5, 11-13, and 19-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al (US Patent No. 5,728,399).

Wu et al disclose the use of bacterial listeriolysin O in conjunction with poly-lysine to deliver a nucleic acid construct to a cell.

Therefore, all of the limitations of the above claims have been anticipated.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1635

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dyer et al. in view of Marasco et al. (US Patent No. 6,143,520) and Mislick et al. (US Patent No. 5,783,566).

The invention of the above claims is drawn to a method of transfecting a cell comprising contacting said cell with a viral vector (HIV or HSV) with a charged carrier such as dermatan sulfate or dextran sulfate.

Dyer et al. disclose the use of dextran sulfate to deliver an HSV vector comprising a gene to cells. Dyer et al. do not teach the HIV vector nor dermatan sulfate.

Marasco et al. teach the use of an HIV vector for transfection.

Mislick et al. teach the use of glycosaminoglycans, such as dermatan sulfate, and modified glycosaminoglycans, such as dextran sulfate to deliver DNA into cells.

It would have been obvious to one of ordinary skill in the art to use HIV vectors or HSV vectors in the methods of Dyer et al. since Marasco et al. teaches that the HIV vector was capable of transfecting a variety of tissues. Moreover, it is known in the art

that virions gain entry into a target cell by recognizing various receptors on the cell surface as demonstrated by Dyer et al. Moreover, one would have expected that the use of dermatan sulfate or dextran sulfate to deliver a virus since the glycosaminoglycans are abundant on the cell surface as taught by Mislick et al. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in using dermatan or dextran sulfates to deliver HIV or HSV based vectors to a target cell.

Therefore, the invention of the above claims would have been *prima facie* obvious over Dyer et al. in view of Marasco et al. (US Patent No. 6,143,520) and Mislick et al. (US Patent No. 5,783,566) without evidence to the contrary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 22, 23, and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 (and dependent claims 22, 23, and 25-27) is indefinite since it depends upon itself.

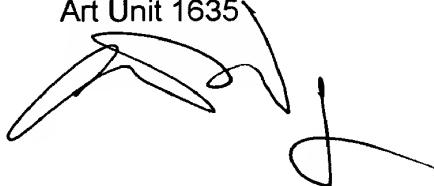
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is 703-306-3217. The examiner can normally be reached on Monday thru Thursday, 6:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

AJW
September 21, 2001

Andrew Wang
Primary Examiner
Art Unit 1635

A handwritten signature in black ink, appearing to read "Andrew Wang", is positioned to the right of the typed name. The signature is fluid and cursive, with a large, stylized 'A' and 'W'.